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No. 02-1007

In The
Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M. J. MADEY,

Respondent.

On Petition For A Writ Of *Certiorari* To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICI CURIAE* CONSUMER PROJECT ON TECHNOLOGY AND PUBLIC KNOWLEDGE IN SUPPORT OF PETITION FOR WRIT OF *CERTIORARI*

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STATEMENT OF INTERESTS OF *AMICI CURIAE*

This brief *amici curiae* in support of petitioner is submitted pursuant to Rule 37 of the Rules of this Court.[1]

Consumer Project on Technology (CPT) is a public interest non-profit organization founded by Ralph Nader in 1995. CPT represents the public who are the ultimate beneficiaries of the invention of new technologies. CPT seeks to protect the public interest concerning intellectual property law in general, and in the fields of pharmaceuticals and biotechnology, computer software and information services in particular.

Public Knowledge (PK) is a public-interest advocacy organization dedicated to fortifying and defending a vibrant information commons. PK works with a wide spectrum of stakeholders to promote the core conviction that some fundamental democratic principles and cultural values – openness, access, and the capacity to create and compete – must be given new embodiment in the digital age.

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[1] Letters from all parties consenting to the filing of this brief have been filed with the Clerk of this Court. No counsel for a party authored this brief in whole or in part, and no person or entity other than *amici curiae*, or their counsel, made a monetary contribution to the preparation or submission of this brief. American University, Washington College of Law, Glushko-Samuelson Intellectual Property Law Clinic students Nathan Mitchler and Cheree Simpson prepared this work under the supervision of Peter Jaszi and Counsel of Record Joshua Sarnoff.

SUMMARY OF ARGUMENT

The Federal Circuit's narrow interpretation of the experimental use exception in *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002), impedes the "Progress of Science and useful Arts." U.S. Const. Art. I, § 8, cl. 8. Under that interpretation, most basic research will not be viewed as strictly philosophical inquiry or will be viewed as furthering a legitimate business purpose. Scientists will need to license essential patented technologies and other research inputs. As a result, basic research will be foregone or delayed.

Basic research is foundational and leads to further discoveries and important inventions. Knowledge is transferred from basic research to additional basic research, applied research, and technology development. Access to patented technologies and other research inputs is essential for basic research. Patent licensing practices increasingly prevent or discourage access to these inputs, precluding or delaying basic research that leads to life-saving technologies and other benefits.

The experimental use exception, like the fair use doctrine in copyright, is needed to promote progress. Courts have continually shaped copyright fair use to respond to changing circumstances in order to effectuate the basic constitutional purpose. The Court should grant the writ of *certiorari* to ensure that the experimental use exception also promotes the constitutional purpose.

ARGUMENT

I. The Federal Circuit's Decision Frustrates the Constitutional Goal of Patent Law.

The premise of patent law is derived from the Constitution: "To Promote the Progress of Science and useful Arts."[2] A patent gives the owner the right to exclude others from making, using, or selling the invention.[3] The grant of a patent creates a legal monopoly in the invention in order to foster innovation.

"Federal patent laws have embodied a careful balance between the need to promote innovation" and the need to provide access to and use of knowledge to enable further innovation.[4] If patent law too strongly favors incentives for initial invention, it discourages sequential invention.[5] The experimental use doctrine is essential for balance because it creates an exception to patent infringement that protects basic research.[6]

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[2] U.S. Const. Art. I, § 8, cl. 8.

[3] 35 U.S.C § 154(a).

[4] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

[5] *See, e.g., Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928) ("the patent monopoly would thus be extended beyond the discovery, and would discourage rather than promote invention").

[6] *See, e.g., Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000); *Roche Prods. Inc., v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935). *See generally* Donald S. Chisum, Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement, § 16.03[1] (2000); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017 (1989).

The Federal Circuit's narrow interpretation of the experimental use exception in this case[7] frustrates the goals of patent law. Under that court's holding, most basic research will not qualify for the experimental use exception. The Federal Circuit limited the exception to strictly philosophical inquiry, which it viewed narrowly, and held the exception inapplicable when the experimental use furthers the researcher's legitimate business, which it viewed broadly.[8] As a result, basic researchers will be forced to seek licenses for a wide range of technologies and other research inputs protected by patent law.

Basic researchers depend upon access to and use of these inputs to perform their research.[9] Restrictive patent licensing practices can inhibit basic research. Access to or use of research inputs may be restricted by: (1) a refusal to license; (2) increased or insurmountable costs; (3) increased time in licensing negotiations and less time in the lab; and (4) onerous licensing offers that discourage licensing.[10] In these circumstances, basic research is foregone or delayed.

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[7] *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002).

[8] *See id.* at 1361-63.

[9] *See* Eisenberg, *supra* note 6, at 1086-87; Linda J. Demaine & Aaron X. Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of Biotechnology Patent*, 55 Stan. L. Rev. 303, 415 (2002).

[10] *See infra* Section II. D.

II. Basic Research, Scientific Progress, and Public Health Are Threatened by the Federal Circuit's Narrow Interpretation.

Basic research expands knowledge and leads to applied research and to beneficial technology. Under the Federal Circuit's holding, basic research cannot occur without licensing patented technology and other research inputs. Basic research and its fruits are thus foregone or delayed. As a result, the Federal Circuit's narrow interpretation of the experimental use exception will stunt basic research, impede progress, and threaten public health.

A. Basic Research Is Vital to Scientific Progress.

Basic research is performed "to gain fundamental knowledge or understanding of phenomena and observable facts, without specific application toward processes or products."[11] Basic research expands knowledge by fostering new ideas and innovative approaches.[12] In contrast, applied research focuses on solving practical problems and developing targeted solutions.[13] Basic research is untargeted,

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[11] 20 U.S.C. § 9501(3)(A).

[12] *See, e.g.*, Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 Am. Bus. L.J. 187, 192 n.13 (2002) ("The objective of basic research is to gain more comprehensive knowledge or understanding of the subject under study, without specific applications in mind.").

[13] *See, e.g.*, Norman W. Storer, The Social System of Science 16 (1966) ("Basic research is the 'purest' form of scientific activity in that it is focused directly upon . . . 'the extension of certified knowledge' rather than upon the solution of practical problems.") (citation omitted).

and is frequently the precursor of more advanced studies that may lead to the development of revolutionary technologies.[14]

Basic research is performed in various settings. In 2000, universities conducted 43 percent of basic research, accounting for 69 percent of all university research and development expenditures. fifty-seven percent of basic research occurred outside of universities.[15]

Basic research has contributed to, and will continue to contribute to, important discoveries and inventions such as the x-ray, the polio vaccine, and genetic engineering.[16] Many advances in medical technology trace their origin to basic research. For example, a study asked ninety physicians to name the most important developments in cardiovascular-pulmonary medicine. The study concluded that 42 percent of the "conceptual steps" of the ten "most important medical treatments," began as basic research by scientists who did not intend to focus their research on that specific disease.[17]

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[14] *See infra* Section II. B.

[15] *See* National Science Foundation, *Science and Engineering Indicators 2002, Academic Research and Development, Highlights, Financial Resources for Academic R&D, at* www.nsf.gov (last visited Jan. 12, 2003).

[16] *See* Arthur Kornberg, *Basic Research, the Lifeline of Medicine, at* www.nobel.se/cgi-bin (last visited Jan. 19, 2003).

[17] National Institute General Medical Sciences, National Institutes of Health, *Why Do Basic Research?, at* www.nigms.nih.gov/news/science_ed/whydo.html (last visited Jan. 19, 2003) [hereinafter cited as *Why Do Basic Research?*]. Three of the most important inventions cited were open-heart surgery, blood vessel surgery, and the drug treatment of hypertension. *See id.*

B. Basic Research Leads to Important Technologies.

Basic research is foundational research. Basic research is essential to applied research and development of important technologies. Information flows from basic research to applied research, and both rely on previous innovations.[18] As Sir Isaac Newton stated, "If I have seen far, it is by standing on the shoulders of giants."[19] If essential prior innovations are not available to complete basic research, then applied research and resulting technological innovations also will be impeded.

Basic research is routinely used in applied research and technology development. For example, in 2000, over 200 universities transferred research to the commercial sector, eight times more than in 1980.[20] In turn, the commercial sector used the information for further basic research, applied research, and technology development.

This flow of information benefits the public. For example, the transfer of knowledge from basic research to applied research to pharmaceutical product development has resulted in important new treatments for "hemophilia, anemia, cystic fibrosis, multiple sclerosis and

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[18] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 698-99 (1998).

[19] *See generally* Robert K. Merton, On the Shoulders of Giants: A Shandean Postscript (Free Press 1965).

[20] *See* Douglas W. Jamison & Christiana Jansen, *Technology Transfer and Economic Growth*, 12 J. Assoc. of Univ. Tech. Managers (2000), *at* www.autm.net/pubs/journal/01/techtransfer.html (last visited Jan. 18, 2003).

heart attacks."[21] Basic research also has led to the discovery and commercial availability of tests for breast cancer and osteoporosis.[22]

Basic research often opens creative fields for future basic and applied research. In 1973, Stanley Cohen and Herbert Boyer invented a method of gene splicing that revolutionized biological research and launched the biotechnology industry.[23] The patent for their gene splicing method was licensed to numerous university, non-profit, and commercial research facilities, including 467 companies.[24] Because this invention was readily licensed and available, innovative products were created such as "insulin for the treatment of diabetes, growth hormone for children with growth deficiencies, and interferon for cancer patients."[25] These developments would not have taken place if Cohen and Boyer had not widely licensed their patent. Without a broad experimental use exception, Cohen and Boyer would have been unable to perform their research if they had been denied the use of essential patented technologies or research inputs.

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[21] Association of University Technology Managers, *Technology Transfer Adds $21 Billion to Economy and Supports 180,000 Jobs a Year* (1997), *at* www.autm.net/pubs/survey/autmre12.html (last visited Jan. 12, 2003).

[22] *See id.*

[23] *See* Stanley N. Cohen, *et al.*, *Construction of Biologically Functional Bacterial Plasmids* In Vitro, 70 Proc. Nat'l Acad. Sci. 3240 (1973).

[24] *See* Law & Technology at GW (George Washington University), *Bertram Rowland and the Cohen/Boyer Cloning Patent*, *at* www.law.gwu.edu/tech/rowland.asp (last visited Jan. 10, 2003).

[25] *Id.*

C. Genetic Research Demonstrates Why Access to Patentable Inputs Is Critical for Basic Research in All Sciences.

Access to technologies and other research inputs is essential for foundational scientific inquiry. Genetic research provides a useful example of a field where such as access is needed. Modern genetic research began with the disclosure in 1953 by James Watson and Francis Crick of the structure of deoxyribonucleic acid.[26] Their discovery led to many advances in genetic research, including the gene splicing methods of Cohen and Boyer. In turn, those methods were used to develop and produce disease-treating materials, such as insulin and growth hormone.[27]

Current basic genetic research requires many technologies and other research inputs that are the subject of patents. For example, such research may require: animal and human gene sequences; bacterial and viral cultures; cell lines; chemical reagents; computerized instruments; data-processing software; diagnostic equipment and materials; gene marking chemicals; gene splicing methods; and laboratory containers and equipment.[28] The need for access to and use of such basic research inputs is more pressing than ever.

In the last two decades, the number of patents has increased dramatically.[29] Subsequent to Cohen and Boyer's

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[26] *See* James D. Watson, The Double Helix: A Personal Account of the Discovery of the Structure of DNA (1968).

[27] *See Why Do Basic Research?*, *supra* note 17.

[28] *See generally* Horace F. Judson, The Eighth Day of Creation: Makers of the Revolution in Biology (1979).

[29] *See, e.g.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1497-98 (2001).

invention, patents became readily available for the results of genetic research.[30] In 2002, the number of biotechnology patents issued numbered over 13,500.[31] As of 2000, the U.S. Patent Trademark Office had granted more than 1,000 patents on human genes and 20,000 more were pending.[32] Many of these patented inventions are necessary for further basic genetic research.

If basic researchers are unable to obtain access to and use of these necessary inputs, their research will be frustrated.[33] This risk is now greater than ever. As the former head of the National Institutes of Health warned in regard to patenting basic research inputs: "[s]uch practices can have detrimental effects on science and its delivery of health benefits."[34]

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[30] *See Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[31] *See* Biotechnology Industry Organization, *Biotechnology Industry Statistics, Guide to Biotechnology, at* www.bio.org/er/ (last visited Jan. 18, 2003).

[32] *See* Merrill Goozner, *Patenting Life*, The American Prospect 26, Dec. 18, 2000.

[33] *See, e.g.*, Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. Rev. 1623, 1670 (2001).

[34] *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary*, 106th Cong. 83 (2000) (Statement of Harold Varmus, President of the Memorial Sloan-Kettering Cancer Center).

D. Patent Licensing Practices Increasingly Block Basic Research.

Licensing practices can create an environment where basic research will not occur.[35] "Patents have a long tradition of being used to *prevent* innovation."[36] Patents are increasingly sought with the intent of creating portfolios (or thickets) to prevent competition.[37] Patent holders may refuse to license necessary inputs to basic research.[38]

The very need to obtain a license may frustrate basic research. Licenses are costly. Licenses must be negotiated, incurring transaction costs and diverting attention from research. Licensing offers may contain restrictions that discourage licensing.

Many basic researchers cannot afford the expense of licensing fees. For example, genetic research scientists may be unable to afford necessary patented gene sequences and

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[35] *See, e.g.*, Heller & Eisenberg, *supra*, note 18, *passim*; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 1, 10-12 (2002).

[36] James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies* 4 (2002), *at* www.papers.ssn.com/sol3/papers-cfm?abstract_id=327760 (last visited Jan. 29, 2003).

[37] *See, e.g.*, Wesley M. Cohen, *et al.*, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)*, National Bureau of Economic Research Working Paper Series 26 (2000); Bessen, *supra* note 36.

[38] *See, e.g.*, Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 Berkeley Tech. L.J. 813, 845-853 (2001). *See generally* John H. Barton, *Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios*, 69 Antitrust L.J. 851, 854, 866 (2002); Marina Lao, *Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty To Deal*, 9 Cornell J. L. & Pub. Policy 193, 202-06, 217-18 (1999).

gene splicing methods. Scientists at Bristol-Meyers Squibb – a well-funded commercial enterprise – were unable to license essential inputs to their cancer research because of the royalty rates demanded by patent holders.[39] Pharmaceutical firms routinely pay millions of dollars for access to gene fragment databases.[40] Most basic researchers are not in a position to pay such high fees. If these scientists cannot pay for access or use, their research cannot be performed.

This problem is especially likely to occur in the field of human genetic research. Most of the human genome has been sequenced. Analysis of these sequences is beginning. As the number of human genome patents increases, more researchers will be unable to fund required inputs to their basic research.[41]

Negotiating licenses is a costly and time consuming enterprise. For critical research inputs, scientists may be willing and able to transfer their time and resources to licensing activity. In other cases, scientists may forego the research.[42] At best, research may be delayed and scientists may waste time better spent on research.

Similarly, patent holders may restrict access to patented inputs unless a researcher agrees to onerous conditions, such as transferring rights to or paying royalties on

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[39] *See* Andrew Pollack, *Bristol-Myers and Athersys Make Deal on Gene Patents*, N.Y. Times, Jan. 8, 2001.

[40] *See* Rebecca S. Eisenberg & Nelson R. Richard, *Public vs. Proprietary Science: A Fruitful Tension?* 131 Daedalus 89, 94 (2002).

[41] *See id.* at 95.

[42] *See, e.g.*, Rai, *supra* note 38, at 831-32.

sequential inventions. Because these restrictions may deprive researchers of the full range of patent incentives, they may refuse to obtain licenses for the needed inputs.[43] Alternatively, substantial time and resources may be wasted negotiating changes to these restrictive conditions.

These licensing practices already have had substantial adverse effects on basic research.[44] The failure to obtain patent licenses has impeded basic genetic research into autism, HIV, and breast cancer.[45] "A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of [basic] research and product development."[46] A narrow interpretation of the experimental use exception will exacerbate the problem.

III. Like Fair Use in Copyright, the Experimental Use Exception Should Promote Progress.

Both the fair use doctrine in copyright[47] and the experimental use exception in patent, properly defined, work to further the constitutional goal of intellectual

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[43] *See* Rebecca S. Eisenberg, *Reaching Through the Genome*, Federal Reserve Bank of Dallas (April 19, 2002), *available at* www.dallasfed.org/htm/dallas/events/archive/eisenberg.pdf (last visited Jan. 30, 2003).

[44] *See* Eliot Marshall, *A Deluge of Patents Creates Legal Hassles for Research*, 287 Science 255, 255-56 (2000).

[45] *See, e.g.*, Lori B. Andrews, *Biotechnology Symposium: The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2002 Hous. J. Health L. & Policy 65, 87 (2002).

[46] Heller & Eisenberg, *supra* note 18, at 698-99.

[47] 17 U.S.C. § 107.

property law – to "Promote the Progress of Science and the useful Arts."[48] Both are judicially-created doctrines designed to effectuate that goal.[49] The fair use doctrine and the experimental use exception "permit[ ] courts to avoid rigid application of the copyright [and patent] statutes when, on occasion [they] would stifle the very creativity which [the] law is designed to foster."[50]

Courts have continually shaped and refined copyright fair use,[51] ensuring that the doctrine performs its intended function. This Court recently reaffirmed the importance of fair use in balancing the monopoly that a copyright holder enjoys and in assuring the promotion of cultural progress.[52] Copyright law can avoid rigid application only when copyright doctrines respond to changing circumstances and are construed in light the Constitution's purposes.[53]

Like creative expression, basic scientific research builds on past work. A properly defined experimental use exception allows basic research to proceed and to be transferred to applied research and new technologies. The experimental use exception should mirror the broad and flexible functioning of the fair use doctrine. This will

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[48] U.S. Const. Art. I, § 8, cl. 8.

[49] *See Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Folsom v. Marsh*, 9 F. Cas. 342 (C.C.D. Mass. 1841).

[50] *Stewart v. Abend*, 495 U.S. 207, 236 (1990).

[51] *See* David Nimmer, Nimmer on Copyright § 13.05 (2002).

[52] *See Eldred v. Ashcroft*, 123 S. Ct. 769, 788-89 (2003).

[53] *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 432 (1984).

better assure that patent law promotes rather than impedes discovery and invention.

CONCLUSION

This Court now has an opportunity to ensure that the experimental use exception functions to promote progress. The Federal Circuit's narrow definition of the experimental use exception must be reconsidered to preserve and promote basic research, scientific progress, and public health. The Court should grant the writ of *certiorari*.

Respectfully submitted,

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